

117TH CONGRESS  
1ST SESSION

# H. R. 5394

To require the Secretary of Health and Human Services to establish a new program which ensures meaningful access to claims data by clinician-led clinical data registries, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2021

Mr. BUCSHON (for himself and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To require the Secretary of Health and Human Services to establish a new program which ensures meaningful access to claims data by clinician-led clinical data registries, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4       This part may be cited as the “Meaningful Access  
5 to Federal Health Plan Claims Data Act of 2021”.

6 **SEC. 2. FINDINGS.**

7       Congress finds as follows:

1                             (1) Clinician-led clinical data registries serve an  
2 important role in promoting, facilitating, and con-  
3 ducting medical research and improving quality of  
4 healthcare by providing timely and actionable feed-  
5 back to practitioners on their performance in rela-  
6 tion to other practitioners and best clinical practices.

7                             (2) Clinician-led clinical data registries are hin-  
8 dered in their ability to promote medical research  
9 and quality improvement by their lack of meaningful  
10 access to claims data.

11                           (3) While the Centers for Medicare & Medicaid  
12 Services has established programs for providing ac-  
13 cess to claims data, those programs fail to provide  
14 clinician-led clinical data registries with meaningful  
15 access to such data.

16                           (4) Ensuring clinician-led clinical data reg-  
17 istries meaningful access to claims data will enable  
18 such entities to better track patient outcomes over  
19 time, expand their ability to assess the safety and ef-  
20 fectiveness of medical treatments, and provide them  
21 with the information necessary to assess the cost-ef-  
22 fectiveness of therapies.

## 1 SEC. 3. ENSURING MEANINGFUL ACCESS TO CLAIMS DATA

2 BY CLINICIAN-LED CLINICAL DATA REG-  
3 ISTRIES.4 (a) ENSURING MEANINGFUL ACCESS TO CLAIMS  
5 DATA.—

## 6 (1) ESTABLISHMENT OF A NEW PROGRAM.—

## 7 (2) ESTABLISHMENT OF A NEW PROGRAM.—

8 The Secretary shall establish a new program (sepa-  
9 rate from any existing data access programs, includ-  
10 ing, without limitation, the Centers for Medicare &  
11 Medicaid Services Qualified Entity (in this section,  
12 referred to as “QE”) Program (42 U.S.C.  
13 1395kk(e), 1395kk–2) (in this section, referred to as  
14 the “Medicare Data Sharing for Performance Meas-  
15 urement Program”) and the Research Data Assist-  
16 ance Center (in this section, referred to as the  
17 “ResDAC”) process) under which the Secretary  
18 shall, at the request of a clinician-led clinical data  
19 registry, provide timely, broad, and continuous ac-  
20 cess to a database of claims data to such clinician-  
21 led clinical data registry for purposes of research,  
22 quality of care measurement and reporting to health  
23 care providers, linking such data with clinical data  
24 and performing risk-adjusted, scientifically valid  
25 analyses and research to support quality improve-  
26 ment or patient safety, and other purposes and uses

1 described herein or approved by the Secretary. Access  
2 to a database of claims data pursuant to this  
3 subsection shall not be more restrictive than access  
4 to data provided under the QE Program or the  
5 ResDAC process.

6 (3) STREAMLINED APPLICATION PROCESS.—

7 (A) INITIAL AND RECERTIFICATION APPLI-  
8 CATION.—Prior to gaining access to a database  
9 of claims data under the program established in  
10 subsection (a), a clinician-led clinical data reg-  
11 istry shall submit to the Secretary an applica-  
12 tion demonstrating that it is qualified (as deter-  
13 mined by the Secretary) to use claims data.  
14 Upon the Secretary's approval of a clinician-led  
15 clinical data registry's application described in  
16 this subparagraph, the Secretary shall provide  
17 access to a database of claims data to such cli-  
18 nician-led clinical data registry for a period of  
19 at least 5 years. After the expiration of the time  
20 period described in this subparagraph, the cli-  
21 cian-led clinical data registry shall reapply to  
22 access the database of claims data under the  
23 program established in subsection (a).

24 (B) PROCESS.—The Secretary shall estab-  
25 lish a streamlined initial application and recer-

1 tification application process under which the  
2 Secretary shall approve or deny the clinician-led  
3 clinical data registry's application described in  
4 subparagraph (2)(A) within 60 calendar days  
5 after receiving the application unless the Sec-  
6 retary demonstrates a compelling reason for  
7 needing additional time to complete the process.  
8 If the clinician-led clinical data registry's appli-  
9 cation described in subparagraph (2)(A) is de-  
10 nied, the Secretary shall provide the reason(s)  
11 for denial.

12 (4) APPEAL RIGHTS.—

13 (A) OPPORTUNITY TO APPEAL.—The Sec-  
14 retary shall develop and maintain a process by  
15 which clinician-led clinical data registries may  
16 appeal—

17 (i) the Secretary's decision to deny  
18 the clinician-led clinical data registry's ap-

19 plication described in subparagraph (2)(A);  
20 and

21 (ii) the Secretary's failure to approve  
22 or deny the clinician-led clinical data reg-

23 istry's application described in subpara-  
24 graph (2)(A) within a reasonable time-

25 frame established by the Secretary.

(b) PERMISSIBLE USES OF CLAIMS DATA.—Clinician-led clinical data registries may—

1                             (1) make available to the public reports evaluating  
2                             the performance of providers of services and suppliers using the claims data provided to such clinician-led clinical data registry under subsection (a)  
3                             in combination with registry data;

4                             (2) use claims data received under subsection  
5                             (a) combined with registry data to conduct additional non-public analyses and provide or charge an access fee for such analyses to authorized users for non-public use;

6                             (3) provide or charge an access fee for data sets  
7                             that link claims data received under subsection (a)  
8                             with registry data to authorized users for non-public  
9                             use; and

10                             (4) provide or charge an access fee for claims data received under subsection (a) to authorized users for non-public use.

11                             (c) FEES.—

12                             (1) CLAIMS DATA PROVIDED TO CLINICIAN-LED CLINICAL DATA REGISTRIES.—Claims data shall be provided to a clinician-led clinical data registry under subsection (a) at a reasonable fee based on the cost of providing such data to the clinician-led clinical data registry. Such fee shall be based at least in part on the number of patients included in

1       the claims data provided to such clinician-led clinical  
2       data registry. Any fee collected pursuant to the pre-  
3       ceding sentence shall be deposited in the Centers for  
4       Medicare & Medicaid Services Program Management  
5       Account.

6                     (2) ANALYSES AND DATA PROVIDED TO AU-  
7       THORIZED USERS.—Clinician-led clinical data reg-  
8       istries may charge a reasonable, cost-based fee for  
9       providing to authorized users claims data, data sets  
10      linking claims data with registry data, or analyses  
11      described in subsection (b).

12                     (d) PROTECTION OF INFORMATION.—

13                     (1) PRIVACY, SECURITY, AND DISCLOSURE  
14      LAWS.—The Secretary shall provide access to a  
15      database of claims data pursuant to subsection (a)  
16      in accordance with applicable information, privacy,  
17      security, and disclosure laws, including, without limi-  
18      tation, the Health Insurance Portability and Ac-  
19      countability Act of 1996, Public Law 104–191, as  
20      amended by the Privacy and Security provisions set  
21      forth in Section 13400 of the Health Information  
22      Technology for Economic and Clinical Health Act,  
23      Public Law 111–5, the regulations promulgated  
24      thereunder codified at 45 CFR Parts 160 and 164,  
25      and subparagraphs (A) through (B) of section

1       105(a)(3) of the Medicare Access and CHIP Reau-  
2       thorization Act of 2015 (42 U.S.C. 1395kk–2(a)(3)).

3                 (2) PROHIBITION ON USING ANALYSES OR DATA  
4       FOR MARKETING PURPOSES.—An authorized user  
5       shall not use analyses or data provided or sold under  
6       paragraphs (2) through (4) of subsection (b) for  
7       marketing purposes.

8                 (3) NO REDISCLOSURE OF ANALYSES OR  
9       DATA.—An authorized user in receipt of an analysis  
10      or datum provided or sold under paragraphs (2)  
11      through (4) of subsection (b) shall comply with sec-  
12      tion 105(a)(5) of Medicare Access and CHIP Reau-  
13      thorization Act of 2015 (42 U.S.C. 1395kk–2(a)(5)).

14                 (4) OPPORTUNITY FOR PROVIDERS OF SERV-  
15      ICES AND SUPPLIERS TO REVIEW.—Prior to a clin-  
16      ician-led clinical data registry using, providing, or  
17      charging an access fee for claims data, data sets  
18      linking claims data with registry data, or analyses  
19      described in subsection (b), to the extent that such  
20      data, data sets, or analyses would individually iden-  
21      tify a provider of services or supplier who is not  
22      being provided or sold such data, data sets, or anal-  
23      yses, such clinician-led clinical data registry shall  
24      confidentially make available such data, data sets, or  
25      analyses to such provider of services or supplier and

1 provide such provider of services or supplier with the  
2 opportunity to appeal and correct errors.

3 (e) DATA USE AGREEMENT.—A clinician-led clinical  
4 data registry and an authorized user shall enter into a  
5 data use agreement regarding the use or disclosure of any  
6 claims data or data sets that link claims data with registry  
7 data that the clinician-led clinical data registry is pro-  
8 viding or charging an access fee to the authorized user  
9 under paragraphs (3) through (4) of subsection (b). Such  
10 agreement shall include the requirements and prohibitions  
11 described in section 105(a)(4) of the Medicare Access and  
12 CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–  
13 2(a)(4)).

14 (f) ASSESSMENT FOR A BREACH.—

15 (1) IN GENERAL.—In the case of a breach of a  
16 data use agreement, the Secretary shall impose an  
17 assessment on the clinician-led clinical data registry  
18 and the authorized user.

19 (2) ASSESSMENT.—The assessment under sub-  
20 section (f)(1) shall be in an amount up to \$100 for  
21 each individual entitled to, or enrolled for, benefits  
22 under part A of title XVIII of the Social Security  
23 Act or enrolled for benefits under part B of such  
24 title for whom the clinician-led clinical data registry  
25 provided data on to the authorized user.

1                             (3) DEPOSIT OF AMOUNTS COLLECTED.—Any  
2                             amounts collected pursuant to this subsection shall  
3                             be deposited in the Federal Supplementary Medical  
4                             Insurance Trust Fund under section 1841 of the So-  
5                             cial Security Act (42 U.S.C. 1395t).

6                             (g) DISCOVERY OR ADMISSION AS EVIDENCE.—  
7                             Claims data released to a clinician-led clinical data reg-  
8                             istry under subsection (a) shall not be subject to discovery  
9                             or admission as evidence in judicial or administrative pro-  
10                             ceedings without consent of the applicable provider of  
11                             services or supplier.

12 **SEC. 4. REPORT TO CONGRESS.**

13                             Not later than 2 years after the date of enactment  
14                             of this Act, and annually thereafter, the Secretary shall  
15                             submit to Congress a report on the extent to which clini-  
16                             cian-led clinical data registries are afforded meaningful ac-  
17                             cess to claims data.

18 **SEC. 5. DEFINITIONS.**

19                             In this Act:

20                             (1) AUTHORIZED USER.—The term “authorized  
21                             user” shall have the meaning ascribed to it in sec-  
22                             tion 105(a)(9)(A) of the Medicare Access and CHIP  
23                             Reauthorization Act of 2015 (42 U.S.C. 1395kk–  
24                             2(a)(9)(A)), as well as a government agency or other  
25                             governmental entity, researchers, entities that seek

1       data for purposes of complying with regulations or  
2       other requirements of the Federal Food and Drug  
3       Administration, and other entities approved by the  
4       Secretary.

5                 (2) CLAIMS DATA.—The term “claims data”  
6       shall have the meaning ascribed to the term “data”  
7       in section 105(b)(1)(B) of the Medicare Access and  
8       CHIP Reauthorization Act of 2015 (42 U.S.C.  
9       1395kk–2(b)(1)(B)).

10               (3) CLINICIAN-LED CLINICAL DATA REG-  
11       ISTRY.—The term “clinician-led clinical data reg-  
12       istry” shall have the meaning ascribed to it in sec-  
13       tion 4005(b) of the 21st Century Cures Act.

14               (4) DATA USE AGREEMENT.—The term “data  
15       use agreement” means an agreement described in  
16       subsection (e) of section 3.

17               (5) NON-PUBLIC USE.—The term “non-public  
18       use” means for the purposes of—

19                         (A) promoting, facilitating, and conducting  
20       medical research; assisting providers of services  
21       and suppliers to improve patient safety and to  
22       develop and participate in quality and patient  
23       care improvement activities, including devel-  
24       oping new models of care;

1                         (B) assisting clinician-led clinical data reg-  
2                         istries in developing and reporting quality meas-  
3                         ures to health care providers quality measures;

4                         (C) educating a government agency or  
5                         other governmental entity; and

6                         (D) supporting clinical trials and other ac-  
7                         tivities necessary to comply with pre- or post-  
8                         market approval or adverse event reporting re-  
9                         quirements or conditions imposed by the Fed-  
10                         eral Food and Drug Administration; and other  
11                         purposes approved by the Secretary.

12                         (6) PROVIDER OF SERVICES.—The term “pro-  
13                         vider of services” shall have the meaning ascribed to  
14                         it in section 1861(u) of the Social Security Act (42  
15                         U.S.C. 1395x(u)).

16                         (7) SECRETARY.—The term “Secretary” means  
17                         the Secretary of Health and Humans Services.

18                         (8) SUPPLIER.—The term “supplier” shall have  
19                         the meaning ascribed to it in section 1861(d) of the  
20                         Social Security Act (42 U.S.C. 1395x(d)).

21                         **SEC. 6. REGULATIONS.**

22                         The Secretary shall promulgate not later than 1 year  
23                         after the enactment of this Act, final regulations to imple-  
24                         ment the provisions of the preceding sections of this Act.

## 1 SEC. 7. COVERAGE OF PROMISING NEW TECHNOLOGIES

## 2 UNDER THE MEDICARE PROGRAM.

3 (a) NON-EXCLUSION OF ITEMS AND SERVICES FUR-  
4 NISHED UNDER ACCESS WITH DATA COLLECTION.—Sec-  
5 tion 1862(a)(1) of the Social Security Act (42 U.S.C.  
6 1395y(a)(1)) is amended—

7 (1) in subparagraph (O), by striking at the end  
8 “and”;

9 (2) in subparagraph (P), by striking the semi-  
10 colon at the end and inserting “, and”; and

11 (3) by adding at the end the following new sub-  
12 paragraph:

13 “(Q)(i) in the case of items and services  
14 for which evidence is promising but not defini-  
15 tive to determine that the items and services  
16 are reasonable and necessary for the diagnosis  
17 or treatment of illness or injury or to improve  
18 the functioning of a malformed body member,  
19 which are not reasonable and necessary for evi-  
20 dence collection to determine that the reason-  
21 able and necessary standard in subparagraph  
22 (A) is met; and

23 “(ii) for purposes of this subparagraph,  
24 evidence collection may include—

25 “(I) evidence of appropriateness, im-  
26 pact on quality of life, effectiveness, safety

1                   or other outcomes as determined by the  
2                   Secretary; and

3                   “(II) evidence derived from real world  
4                   data repositories, patient registries, cohort  
5                   studies, randomized controlled trials, or  
6                   other studies as determined by the Sec-  
7                   retary;

8                   “(iii) the evidence collection described in  
9                   clause (ii) shall be evidence collection approved  
10                  by the Secretary acting through the Adminis-  
11                  trator of the Centers for Medicare & Medicaid  
12                  Services in collaboration with the Director of  
13                  the Agency for Healthcare Research and Qual-  
14                  ity as meeting the priorities of this title as set  
15                  forth under Section 1142;

16                  “(iv) such evidence collection shall be time-  
17                  limited to a period of no more than 5 years, un-  
18                  less the Secretary deems that extension is need-  
19                  ed to address remaining gaps in evidence;

20                  “(v) such evidence collection shall be acces-  
21                  sible, include outcomes relevant to patients, and  
22                  have transparent governance; and

23                  “(vi) such evidence collection shall be re-  
24                  ferred to as ‘Access with Data Collection’.”.

1       (b) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply to items and services furnished  
3 after December 31, 2021.

